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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,800	03/30/2005	David C Racenet	2863(203-3511)	5353

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Tyco Healthcare Group LP
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EXAMINER

LOPEZ, MICHELLE

ART UNIT	PAPER NUMBER
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3721

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,800	Applicant(s) RACENET, DAVID C	
	Examiner Michelle Lopez	Art Unit 3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26 and 29-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26 and 29-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/9/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the amendment filed on 9/29/08.
2. Claims 27-28 have been canceled.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 6/9/08 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 26 and 29-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin (US 6835199) in view of Hooven (US 5433721) and in view of Bolanos (US 5690269). McGuckin discloses the claimed tool assembly comprising an anvil (50) and a cartridge (40) assembly, the cartridge (40) having a plurality of fasteners and being movable in relation to the anvil (50) between a spaced position and an approximated position, the cartridge and anvil defining a tissue gap between them in the approximated position; a clamp member (60) movable from a first to a second position configured to maintain the proximal end of the cartridge and the anvil in juxtaposed alignment, i.e. placed close together, when the clamp member is in the second position; a dynamic clamping member (70) movably with relation to the

Art Unit: 3721

cartridge and anvil, configured to define a maximum tissue gap between the cartridge and anvil during ejection of fasteners as shown in figs. 13-15.

With respect to claim 26, while McGuckin discloses drive members connected to the clamp and dynamic members being formed from cable (64) and flexible member (80), respectively, McGuckin fails to disclose a drive member connected to both the clamp member and the dynamic clamping member. Hooven teaches the concept of a tool assembly for a surgical instrument including a clamp member (77), a dynamic clamping member (82, 83, 86), and a drive member (71) connected to both the clamp and the dynamic clamping members for the purposes evenly applying fasteners to tissue during endoscopic surgery.

Furthermore, the modified invention of McGuckin in view of Hooven, fails to disclose wherein the drive member includes a coaxial drive cable, the coaxial drive cable including an outer sheath and a center rod. Bolanos teaches the concept of a tool assembly having a drive member with a coaxial drive cable including an outer sheath (200) and a center rod (70) for the purpose enhancing the flexibility of said drive member. The modification of McGuckin in view of Hooven (to provide a single drive member), and further by substituting said drive member for a coaxial cable such as shown by Bolanos would have been obvious because the substitution of one known and equivalent mechanism (coaxial cable as shown by Bolanos) for another (rotatable cables as shown by McGuckin and Hooven) would have yielded predictable results to one of ordinary skill in the art at the time of the invention and the technique for improving a particular class of devices was part of the ordinary capabilities of a person skill in the art. In the instance case, to provide a drive member as a coaxial cable including an outer sheath and a center rod, as taught by Bolanos, would be for the benefits of providing a simple and reliable drive mechanism,

Art Unit: 3721

enhancing the flexibility of it, while at the same time providing sufficient rigidity to transfer force without buckling.

With respect to claims 29-30, Bolanos also teaches wherein the center rod (70) is movable and axially movable with respect to the outer sheath.

With respect to claim 31, it is deemed that Bolanos' center rod (70) is rotatable in relation to the outer sheath as shown in Fig. 8.

With respect to claims 32-33, Hooven shows wherein a portion (71) is operably connected to a clamp member (77) and wherein a portion (73) is operably connected to the dynamic clamping member (82, 83, 86).

With respect to claim 34, McGuckin discloses wherein the tool assembly (16) is pivotally secured via (14) to a body portion (at the proximal end of 12) of a stapling device.

With respect to claims 35-36, Bolanos also shows wherein the tool assembly (20) is operably connected to a collar member (16) and the collar member is pivotally secured to a body portion (14) of the stapling device, and the tool assembly is rotatably mounted to the collar member as shown in fig. 8.

With respect to claim 37, Bolanos also shows wherein rotation of the coaxial cable (70, 200) effects rotation of the tool assembly as shown in fig. 8 and col. 6; lines 9-16.

With respect to claims 38-39, McGuckin discloses wherein the dynamic clamping member includes a first and a second flange as shown in figs. 13-15; and wherein the clamp

Art Unit: 3721

member (60) is annular and is positioned about a proximal end of the anvil and cartridge assembly.

With respect to claims 40-41, the modified invention of McGuckin does not specifically disclose the outer sheath is selected from the group consisting of steel mesh, plastic, nitinol, and Kevlar. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided an outer sheath as claimed, since it has been held to be within the general skill in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice.

With respect to claims 42-43, McGuckin discloses a knife blade (84a) formed on the dynamic clamping member.

With respect to claim 44, Bolanos also shows a drive collar (16) wherein the outer sheath (200) is fixedly attached to a drive collar as shown in Fig. 12 (claim 44).

With respect to claim 45, McGuckin discloses wherein the first position of the dynamic clamping member is adjacent a proximal end of the tool assembly and the second position is adjacent to a distal end of the tool assembly as shown in figs. 13-15; and wherein the cartridge has a plurality of staples (120) and pushers (118) as shown in fig. 15.

With respect to claims 46-47, McGuckin discloses wherein the cartridge assembly includes a sled (via proximal end of flange 82a), and at least one pusher 118 associated with each of the plurality of fasteners, the sled being driving by the dynamic clamping member (70) into engagement with each of the pushers as shown in fig. 15.

Art Unit: 3721

5. Claims 48-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuckin (US 6835199) in view of Bolanos (US 5690269). McGuckin discloses the claimed tool assembly comprising an anvil (50) and a cartridge (40) assembly, the cartridge (40) having a plurality of fasteners and being movable in relation to the anvil (50) between a spaced position and an approximated position, the cartridge and anvil defining a tissue gap between them in the approximated position; a clamp member (60) movable from a first to a second position configured to maintain the proximal end of the cartridge and the anvil in juxtaposed alignment, i.e. placed close together, when the clamp member is in the second position; a dynamic clamping member (70) movably with relation to the cartridge and anvil, configured to define a maximum tissue gap between the cartridge and anvil during ejection of fasteners as shown in figs. 13-15.

With respect to claim 48, while McGuckin shows wherein the flange portions have an arcuate edge portion, McGuckin fails to disclose wherein at least one of the upper or lower flange portions has an arcuate cross-section along an axis traverse to a longitudinal axis of the cartridge assembly. It would have been an obvious matter of design choice to have changed the shape of the flange portions to have an arcuate cross section as claimed, since such a modification would have involve a mere change in the shape of a component. A change in shape is generally recognized as being within the level of ordinary skill in the art. The change in shape would be for the benefit of matching a respective arcuate surface of either the anvil or cartridge assembly, if desired.

With respect to claims 49-50, McGuckin discloses a knife blade (84a) formed on the central body portion of the dynamic clamping member (70).

Art Unit: 3721

With respect to claims 51-52, McGuckin discloses wherein the cartridge assembly includes a sled (via proximal end of flange 82a), and at least one pusher 118 associated with each of the plurality of fasteners, the sled being driving by the dynamic clamping member (70) into engagement with each of the pushers as shown in fig. 15.

With respect to claim 53-54, McGuckin discloses wherein the upper and lower flanges are substantially vertically aligned as shown in fig. 14, and the knife blade (84a) is disposed on the central body portion between the upper and lower flanges.

Response to Arguments

6. Applicant's arguments filed 9/29/08 have been fully considered but they are not persuasive. Applicant argues that Bolanos does not teach or suggest providing a coaxial drive cable to move a clamp member and a dynamic clamping member, and wherein McGuckin also fails to disclose such a drive member. This is not agree with by the examiner for the reasoning set forth above in the rejection.

7. For the reasons above, the grounds of rejection are deemed proper.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

Art Unit: 3721

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Lopez whose telephone number is 571-272-4464. The examiner can normally be reached on Monday - Thursday: 8:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on 571-272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Lopez/
Examiner, Art Unit 3721

/Rinaldi I Rada/
Supervisory Patent Examiner, Art Unit 3721